



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0084]

Submission of Extended Digital Electrocardiogram Waveform Data; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to consider changes in how digital electrocardiogram (ECG) data gathered to assess a drug's adverse effects on heart function should be submitted for review. At the meeting, an extension of the Health Level-7 (HL7) Annotated ECG standard data format--used by the ECG warehouse--will be presented. The new data format is intended to facilitate electronic submission and sharing of ECG data from continuous recordings. We encourage device manufacturers, ECG laboratories, investigators, industry, and academic researchers to offer advice on the proposed format and perspective on the collection, analysis, submission, and review of data from long-term continuous ECG recordings for assessing the safety of investigational drugs.

Date and Time: The public meeting will be held on Wednesday, March 14, 2012, from 8 a.m. to 5 p.m.

Location: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 2, rm. 2031, Silver Spring, MD 20993.

Contact Person: Devi Kozeli, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4183, Silver Spring, MD 20993-0002, 301-796-1128, FAX: 301-796-9841, email: Devi.Kozeli@fda.hhs.gov.

Attendance and Registration: The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Therefore, early arrival is encouraged. There is no fee to attend the meeting, and attendees who do not wish to make an oral presentation do not need to register. Seating will be on a first-come, first-served basis.

If you would like to make an oral presentation during the meeting, you must register by sending an email to devi.kozeli@fda.hhs.gov by February 14, 2012. Your email should contain complete contact information for each attendee, including name, title, affiliation, address, email address, and phone number. We will try to accommodate all persons who wish to make a presentation. Registrants will receive confirmation after they have been selected. Persons registered to make an oral presentation should check in before the meeting. If you need special accommodations because of a disability, please contact Devi Kozeli (see Contact Person) at least 7 days before the meeting.

Comments: Interested persons may submit either electronic or written comments regarding this document. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. To ensure consideration, all comments must be received by March 28, 2012.

SUPPLEMENTARY INFORMATION:

I. Background

Some drugs are known to interfere with the electrical function of the heart by delaying cardiac repolarization, and this delay may be associated with serious and sometimes fatal adverse events. Delay in cardiac repolarization can be assessed with an ECG, a recording of the cyclical changes in the heart's electrical activity. The delay is quantified as the increase in the Q wave and T wave (QT) interval, the length of time corresponding to the start of the Q wave and the end of the T wave on the ECG tracing. In 2005, FDA issued a guidance that was developed within the Expert Working Group of the International Conference on Harmonization of Technical Requirements (ICH) that made recommendations for the gathering and submission of ECG data, the clinical evaluation of the QT interval, and reporting of adverse events.

In responding to this guidance (ICH E-14), investigators of the efficacy and safety of drugs typically submit digitized 10-second ECGs taken at key protocol time points to FDA's ECG Warehouse. These ECGs are often extracted from continuous ECG recordings collected on Holter, Telemetry, and other long-term monitoring devices. ECG information submitted through the ECG warehouse should be in a format that was jointly developed by FDA, sponsors, core laboratories, and device manufactures under the auspices of HL7, an international organization of information scientists who collaborate to create standards for the exchange of electronic healthcare information.

Because effects on heart function that are only apparent in long-term ECG data from continuous recordings have been shown to be important in the evaluation of drug efficacy and safety, FDA plans to request these data whenever they are collected in clinical trials. This will necessitate changes in the HL7 Annotated ECG.

II. Purpose and Scope of the Meeting

The HL7 Annotated ECG data format will be discussed, and changes to it for handling long-term ECG data from continuous recordings will be proposed. The revised format is expected to proceed through the standard approval processes of HL7. Needed expansions to the hardware and software resources of FDA's ECG Warehouse and modifications to the upload process for ECG data are underway. FDA is interested in the perspective of manufacturers, ECG laboratories, investigators, industry, and academic researchers as it seeks to improve the collection, analysis, submission, and review of continuous ECG recordings for purposes of assessing drug safety.

Dated: February 2, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-2756 Filed 02/06/2012 at 8:45 am; Publication Date: 02/07/2012]